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10/559,373	02/07/2006	Nobuaki Sumiyoshi	2005_1741A	3630

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EXAMINER	
KASSA, TIGABU	

ART UNIT	PAPER NUMBER
1619	

NOTIFICATION DATE	DELIVERY MODE
01/21/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/559,373	SUMIYOSHI ET AL.	
	Examiner	Art Unit	
	TIGABU KASSA	1619	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 October 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *24,30,31 and 37* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *24,30,31 and 37* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/18/10*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Formal Matters

Applicant's amendment filed on 10/18/2010 is acknowledged and has been fully considered. **Claims 24, 30-31, and 37 are pending. Claims 24, 30-31, and 37 are under examination in the instant office action**. Claims 1-23, 25-29, 32-36 are cancelled. Applicant has newly amended claims 24 and 31. Applicant's amendment has necessitated a new ground of rejection.

Withdrawn Rejection

All rejections applied in the previous office action are hereby withdrawn as a result of applicant's claim amendment filed on 10/18/2010.

Moot Rejections/Objections

All rejections and/or objections of claims 1-23, 25-29, 32-36 cited in the previous office action mailed on June 16, 2010 are moot, because said claim(s) has/have been cancelled.

Information Disclosure Statement

The information disclosure statements (IDS) submitted on 10/18/10 is acknowledged. Accordingly, the examiner has considered the references. A Signed copy is attached.

New Claim Rejections – Necessitated by Amendment

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The factual inquiries set forth in Graham **v.** John Deere Co., 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness

All prior art references have been cited previously in the record except Panter-Brick (Europ. J. Intensive Care Medicine 2, 45-51, 1976) and Kido et al., (US Patent No. 6129925, published on October 10, 2000).

Claims 24 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Segers et al., (US Patent 5383324, published on January 24, 1995), Veech (US Patent No. 4663166, published on May 5, 1987), Nakamura et al., (US Patent 6867193, published on March 15, 2005), Panter-Brick (Europ. J. Intensive Care Medicine 2, 45-51, 1976), and Kido et al., (US Patent No. 6129925, published on October 10, 2000).

Applicant Claims

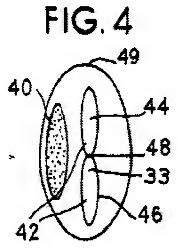
Applicant claims in instant claim 24 an aseptic combination preparation to be mixed at the time of use by opening a partition wall which separates two or more chambers of a container comprising a first solution containing dipotassium hydrogen phosphate, glucose, sodium chloride, sodium lactate, calcium gluconate, and magnesium and zinc sulfate in a first chamber and a second solution containing dipotassium hydrogen phosphate and at least one amino acid selected from the list in a second chamber, wherein the first solution and the second solution each have a potassium ion concentration of about 13 to 35 mEq/L.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

Segers et al., teach a system designed to be used for any medical procedure requiring bicarbonate, and especially for peritoneal dialysis comprising a container with two chambers (see Figure 4). Segers et al., teach the chambers as follows (column 7, lines 19-26):

> upper chamber **44** and a lower chamber **46**.
> In an embodiment, the multi-chamber container **42** has a frangible seal **48** between the upper chamber **44** and the lower chamber **46**. Opening the frangible seal **48** provides fluid communication between the upper chamber **44** and the lower chamber **46**. The multi-chamber **42** houses at least two non-compatible solutions that after mixture will result in a ready-to-use dialysis solution. An example of the multi-chambered container **42** is set

Segers et al., teach although all of the systems disclosed herein are designed to be used for any medical procedure requiring bicarbonate, and especially peritoneal dialysis, the embodiment illustrated in FIG. 4 is conveniently used for CAPD (column 7, lines 30-34).



To this end, in an embodiment, **the upper chamber 44 contains calcium chloride and magnesium chloride, whereas the lower container 46 contains bicarbonate (column 7, lines 34-37). In a preferred embodiment, the upper chamber 44 can further include sodium chloride, potassium chloride, dextrose and dextrose polymers (column 7, lines 37-39. Likewise, the lower chamber 46 can further include sodium chloride, potassium chloride, amino acids, peptides and glycerol** (column 7, lines 39-41).The examiner notes that from the above teachings the required solutions of a potassium salt and sugar in one chamber and a potassium salt and an amino acid in another chamber are clearly meet.

Segers et al., teach, for example, in an embodiment, when the solution contained in the upper chamber 44 is mixed with the solution contained in the lower chamber 46, the subsequent peritoneal dialysis solution has the following composition: 15.0 to about 45.0 (mmol/L)

bicarbonate; 90.0 to about 110.0 (mmol/L) chloride; **90.0 to 142.0 (mmol/L) sodium**; 0.0 to about 2.0 (mmol/L) calcium; 0.0 to about 1.0 (mmol/L) magnesium; **0.0 to about 3.0 (mmol/L) potassium**; 0**.0 to about 4.0% amino acids; 0.0 to about 4.0% peptides**; 0.0 to about 4.0% glycerol; **0.0 to about 5.0% dextrose; and 0.0 to about 10.0% dextrose polymers**. Segers et al., teach ten grams of **sodium bicarbonate** is enough to generate two liters of carbon dioxide and will therefore, in the systems set forth in FIGS. 2-5, stabilize a bicarbonate solution for several months to years (column 5, lines 62-66).

Ascertainment of the Difference between Scope the Prior Art and the Claims (MPEP §2141.012)

Although Segers et al., teach the incorporation of potassium in concentration 0.0 to about 3.0 (mmol/L) in the final mixture, which the examiner believes would be expected to behave similarly as in the instantly recited concentration ranges, Segers et al., do not explicitly teach the concentrations of potassium ion in each chamber from about 13 to 35 mEq/L. Segers et al., is silent with regard to the concentration of the potassium ion in each chamber. These deficiencies are cured by the teachings of Veech.

Veech teaches electrolyte solutions are provided which are useful in electrolyte and fluid therapy, parenteral nutrition, and dialysis (see abstract). **Veech teaches electrolyte solution compositions for example in column 35 table III on the example with broader range contains 0 to about 90 millimoles/L. Veech teaches the electrolyte solutions of such Table III, as indicated above, are useful in such applications as intravenous administration for**

replacement of electrolytes and fluids, for parenteral nutrition, for dialysis, and the like (column 35, lines 62-65).

Segers et al., is silent whether the material is plastic or not as recited in instant claim 30. Segers et al., even if they teach the incorporation of amino acids, Segers et al., are silent on specific list of amino acids. These deficiencies are cured by the teaching of Nakamura et al.

Nakamura et al teach a preparation contained in a plastic bag with two chambers which are separated by a seal which can be opened in order to mix the contents of the two chambers. One chamber contains a solution of amino acids and the other contains albumin (column 4, lines 18-36). Branched amino acids in the present invention include amino acids having a branched alkyl group in the side chain thereof, that is, L-valine, L-leucine or L-isoleucine, and any of these amino acids can be used. Other amino acids are aliphatic amino acids such as straight-chain amino acids (glycine, L-alanine), hydroxy amino acids (L-serine, L-threonine), acidic amino acids (L-aspartic acid, L-glutamic acid), amido-type amino acids (L-asparagine, L-glutamine), basic amino acids (L-lysine, L-hydroxy lysine, L-arginine), and sulfur-containing amino acids (L-cystein, L-cystine, L-methione) (column 2, lines 26-40).

Although Segers et al., teach **the upper chamber 44 contains calcium chloride and magnesium chloride, whereas the lower container 46 contains bicarbonate (column 7, lines 34-37)**. **In a preferred embodiment, the upper chamber 44 can further include sodium chloride, potassium chloride, dextrose and dextrose polymers (column 7, lines 37-39)**. **Likewise, the lower chamber 46 can further include sodium chloride, potassium chloride,**

amino acids, peptides and glycerol (column 7, lines 39-41), Segers et al., do not teach the incorporation of dipotassium hydrogen phosphate in both chambers. Segers et al., do not teach also the incorporation of sodium lactate, calcium gluconate, magnesium sulfate, and zinc sulfate. These deficiencies are cured by the teachings of Kido et al., and Panter-Brick.

Kido et al., teach an infusion preparation set (a container filled with infusion liquids) useful for preparation of an infusion liquid containing **sugars, amino acids, electrolytes, a fat emulsion and vitamins** (see abstract). Kido et al., teach that examples of the amino acids include various amino acids (essential and non-essential amino acids) which have been used in conventional amino acid infusion preparations for supplying the living body with nutrients, such as L-isoleucine, L-leucine, L-valine, L-lysine, L-methionine, L-phenylalanine, L-threonine, L-tryptophan, L-arginine, L-histidine, glycine, L-alanine, L-proline, L-aspartic acid, L-serine, L-tyrosine, L-glutamic acid, L-cysteine and the like (column 5, lines 48-67). Various types of water soluble salts which have been used in the prior art infusion preparations can be used as electrolytes, including **chlorides, sulfates, acetates, gluconates, lactates and the** like, water soluble salts of various inorganic components such as sodium, potassium, calcium, magnesium, zinc, iron, copper, manganese, iodine, phosphorus and the like, which are considered to be essential for the maintenance of biological functions and electrolyte balance in the body fluid (column 6, lines 1-10). The preferred electrolyte components include the following compounds: Sodium: **sodium chloride, sodium lactate**, sodium acetate, sodium sulfate and sodium glycerophosphate; Calcium: **calcium gluconate, calcium chloride**, calcium glycerophosphate, calcium lactate, calcium pantothenate and calcium acetate; Magnesium: **magnesium sulfate, magnesium chloride**, magnesium glycerophosphate, magnesium acetate and magnesium lactate;

Zinc: **zinc sulfate**, zinc chloride, zinc gluconate, zinc lactate and zinc acetate (column 6, lines 23-44).

Panter-Brick teaches intravenous nutrition of metabolic mineral composition containing calcium lactate, **dipotassium hydrogen phosphate**, disodium hydrogen phosphate, **magnesium sulfate, calcium chloride, zinc sulfate** etc. (page 47 Table 5).

Finding of Prima Facie Obviousness Rationale and Motivation (MPEP §2142-2143)

It would have been prima facie obvious to a person of ordinary skill in the art at the time of the instant invention was made to modify the teachings of Segers et al., via incorporating potassium ion in concentration range as recited in instant claim 24 because Veech teaches an electrolyte solution that contains 0 to about 90 mEq/L of potassium ion. An ordinary skilled artisan would have been motivated to incorporate potassium in concentration range as recited in instant claim 24 because Veech teaches that **the electrolyte solutions of such Table III, as indicated above, are useful in such applications as intravenous administration for replacement of electrolytes and fluids, for parenteral nutrition, for dialysis, and the like** (column 35, lines 62-65). Furthermore, in the case where the claimed ranges for the amounts of the ingredients "overlap or lie inside ranges disclosed by the prior art" a prima facie case of obviousness exists. In re Wertheim, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); In re Woodruff, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990). Similarly, a prima facie case of obviousness exists where the claimed ranges and prior art ranges do not overlap but are close enough that one skilled in the art would have expected them to have the same properties. Titanium Metals Corp. of America v. Banner, 778 F.2d 775, 227 USPQ 773 (Fed. Cir. 1985). Furthermore, differences

in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). One of ordinary skill in the art would have had a reasonable chance of success in combining the teachings of Segers et al. and Veech because both references teach electrolyte solutions for use in dialysis.

It would have been prima facie obvious to a person of ordinary skill in the art at the time of the instant invention was made to modify the teachings of Segers et al. by incorporating the specific amino acids recited in instant claim 27 because Nakamura et al. teach medicinal preparations which contain for example amino acids as specified above contained in two or more adjacent chambers which are mixed just prior to use. It would have been prima facie obvious to a person of ordinary skill in the art at the time of the instant invention was made to use plastic containers to deliver such electrolyte solutions in dialysis because plastic are conventionally known in the art for holding solutions. An ordinary skilled artisan would have been motivated to incorporate these amino acids because they are conventionally known and are sources of proteins. An ordinary skilled artisan would have had a reasonable expectation of success upon combination of the prior art teachings, because both Segers et al. and Nakamura et al. teach medicinal preparations which contain for example amino acids contained in two or more adjacent chambers which are mixed just prior to use.

It would have been prima facie obvious to a person of ordinary skill in the art at the time of the instant invention was made to modify the teachings of Segers et al., by incorporating

sodium lactate, calcium gluconate, magnesium sulfate, and zinc sulfate in the first chamber because Kido et al., teach an infusion preparation set (a container filled with infusion liquids) useful for preparation of an infusion liquid containing **sugars, amino acids, electrolytes, a fat emulsion and vitamins** (see abstract), wherein the preferred electrolyte components include the following compounds: Sodium: **sodium chloride, sodium lactate**, sodium acetate, sodium sulfate and sodium glycerophosphate; Calcium: **calcium gluconate, calcium chloride**, calcium glycerophosphate, calcium lactate, calcium pantothenate and calcium acetate; Magnesium: **magnesium sulfate, magnesium chloride**, magnesium glycerophosphate, magnesium acetate and magnesium lactate; Zinc: **zinc sulfate**, zinc chloride, zinc gluconate, zinc lactate and zinc acetate (column 6, lines 23-44). One of ordinary skill in the art would have been motivated to incorporate sodium lactate, calcium gluconate, magnesium sulfate, and zinc sulfate because these water soluble salts according to Kido et al., are considered to be essential for the maintenance of biological functions and electrolyte balance in the body fluid (column 6, lines 7-10). An ordinary skilled artisan would have had a reasonable expectation of success upon combining the teachings of Segers et al., and Kido et al.,, because both references are teaching similar compositions such as electrolyte salts and amino acids.

It would have been prima facie obvious to a person of ordinary skill in the art at the time of the instant invention was made to modify the teachings of Segers et al., by incorporating dipotassium hydrogen phosphate in both chambers because Panter-Brick teaches intravenous nutrition of metabolic mineral composition containing calcium lactate, **dipotassium hydrogen phosphate**, disodium hydrogen phosphate, **magnesium sulfate, calcium chloride, zinc sulfate** etc. (page 47 Table 5). One of ordinary skill in the art would have been motivated to incorporate

dipotassium hydrogen phosphate because as conventionally known in the art dipotassium hydrogen phosphate is a physiologically compatible salt which is used for making a buffering system or adjustment of pH of a given solution. Furthermore, the dipotassium hydrogen phosphate would be an excellent source of electrolytes such as potassium and phosphates. An ordinary skilled artisan would have had a reasonable expectation of success upon combining the teachings of Segers et al., and Panter-Brick, because both references teach similar compositions containing electrolyte salts as delineated above.

In light of the forgoing discussion, one of ordinary skill in the art would have concluded that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a). Therefore, the invention would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the reference, especially in the absence of evidence to the contrary.

Claims 31 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Segers et al. (US Patent 5383324), Nakamura et al., (US Patent 6867193, published on March 15, 2005), Kido et al., (US Patent No. 6129925, published on October 10, 2000), and Stone et al. (US Patent 4489097, published on December 18, 1994).

Applicant Claims

Applicant claims in instant claim 31 an aseptic combination preparation to be mixed at the time of use by opening a partition wall which separates two or more chambers of a container, comprising a first solution containing a sodium salt and a sugar sodium chloride, glucose,

calcium chloride and magnesium chloride in a first chamber and a second solution containing a sodium salt and a bicarbonate salt sodium chloride, sodium hydrogen carbonate, potassium dihydrogen phosphate and potassium chloride in a second chamber, wherein the first solution and the second solution each have an osmotic pressure ratio of about 1 relative to physiological saline.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

The teachings of Segers et al., are set forth above.

Ascertainment of the Difference Between Scope the Prior Art and the Claims (MPEP §2141.012)

Segers et al., do not teach an osmotic pressure ratio of about 1. Segers et al., are also silent whether the material is plastic or not. These deficiencies are cured by the teaching of Nakamura et al.

Nakamura et al teach a preparation contained in a plastic bag with two chambers which are separated by a seal which can be opened in order to mix the contents of the two chambers. One chamber contains a solution of amino acids and the other contains albumin (column 4, lines 18-36). In example 1, the osmotic pressure ratio between the amino acid and the albumin containing solutions was 2.8-3.3 (column 5, lines 8-14).

Although Segers et al., teach the incorporation of dextrose, Segers et al., do not teach the inclusion of glucose.

Kido et al., teach an infusion preparation set (a container filled with infusion liquids) useful for preparation of an infusion liquid containing **sugars, amino acids, electrolytes, a fat emulsion and vitamins** (see abstract). Various types of sugars may be used as sugars contained

in the infusion liquid included in the first compartment (column 4, lines 64-65). Reducing sugars such as **glucose**, fructose, maltose and the like are particularly preferred 9column 4, lines 66-67).

Although Segers et al., teach the incorporation of potassium chloride as one of the salts, Segers et al. do not teach potassium dihydrogen phosphate as the potassium salt. This deficiency is cured by the teaching of Stone.

Stone teaches sterile compositions intended for administration to humans or lower animals to minimize bacterial and mycotic contamination which can cause infections associated with the medical and veterinary use of such compositions (see abstract). Stone teaches the **compositions are useful for all purposes where contact between electrolyte solutions or nutrient solutions and blood or internal organs or systems is required, e.g., as plasma expanding agents, as the fluid medium in kidney dialyzers, as irrigation solutions for cleansing wounds, as respirator solutions, and the like** (column 5, lines 50-58). Stone teaches an intravenous electrolyte solution containing potassium dihydrogen phosphate, potassium chloride, and other salts and sugar (column 12, example 1, lines 45-60).

Finding of Prima Facie Obviousness Rationale and Motivation (MPEP §2142-2143)

It would have been prima facie obvious to a person of ordinary skill in the art at the time of the instant invention to ensure that the osmotic pressure ratio between the two solutions because Nakamura et al. teach an osmotic pressure ratio of 2.8-3.3 between two solutions of a medicinal preparation contained in adjacent chambers until mixing just prior to use. An ordinary skilled artisan would have been motivated to adjust the osmotic pressure of the solutions because

the osmolality of medicinal preparations is important for the safety and efficacy of the preparation. Moreover, the instant specification points out that the administration of solutions of the incorrect osmolality due to medical error is already a well known medical problem. The examiner notes that the original specification does not contain a definition to the term "about". The examiner contends that 2.8-3.3 reads on and renders obvious about 1. Similarly, a prima facie case of obviousness exists where the claimed ranges and prior art ranges do not overlap but are close enough that one skilled in the art would have expected them to have the same properties. Titanium Metals Corp. of America v. Banner, 778 F.2d 775, 227 USPQ 773 (Fed. Cir. 1985). Furthermore, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). An ordinary skilled artisan would have had a reasonable expectation of success upon combination of the prior art teachings, because both Segers et al. and Nakamura et al. teach medicinal preparations which contain for example amino acids contained in two or more adjacent chambers which are mixed just prior to use.

It would have been prima facie obvious to a person of ordinary skill in the art at the time of the instant invention was made to modify the teachings of Segers et al., by incorporating glucose in the first chamber because Kido et al., teach an infusion preparation set (a container filled with infusion liquids) useful for preparation of an infusion liquid containing **sugars, amino acids, electrolytes, a fat emulsion and vitamins** (see abstract), wherein various types of sugars may be used as sugars contained in the infusion liquid included in the first compartment (column

4, lines 64-65). Reducing sugars such as **glucose**, fructose, maltose and the like are particularly preferred (column 4, lines 66-67). One of ordinary skill in the art would have been motivated to substitute dextrose with glucose because they are functionally equivalent. Furthermore, glucose is a conventionally known source of sugar. An ordinary skilled artisan would have had a reasonable expectation of success upon combining the teachings of Segers et al., and Kido et al.,, because both references are teaching similar compositions such as electrolyte salts, amino acids, and sugars.

It would have been prima facie obvious to a person of ordinary skill in the art at the time of the instant invention was made to modify the teachings of Segers et al. by incorporating potassium dihydrogen phosphate as recited in instant claim 31 because Stone teaches in a similar electrolyte solution incorporating potassium dihydrogen phosphate as set forth above. One of ordinary skill in the art would have been motivated to substitute potassium chloride with potassium dihydrogen phosphate because they are functionally equivalent potassium salts. One of ordinary skill in the art would have been motivated to incorporate potassium dihydrogen phosphate because it is a conventional source of electrolytes. An ordinary skilled artisan would have had a reasonable expectation of success upon combination of the prior art teachings, because both Segers et al. and Stone teach similar electrolyte solutions that can be used in dialysis containing potassium salts, sodium salts, and sugar.

In light of the forgoing discussion, one of ordinary skill in the art would have concluded that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a). Therefore, the invention would have been prima facie obvious to

one of ordinary skill in the art at the time the invention was made, as evidenced by the reference, especially in the absence of evidence to the contrary.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TIGABU KASSA whose telephone number is (571)270-5867. The examiner can normally be reached on 9 am-5 pm Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Robert A. Wax can be reached on 571-272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Tigabu Kassa 01/16/11

/Cherie M. Woodward/
Primary Examiner, Art Unit 1647